

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 5 1995

Mr. J. Scott Thenell
Regulatory Affairs Manager
DNA Plant Technology Corporation
6701 San Pablo Avenue
Oakland, CA 94608

Dear Mr. Thenell:

This is in regard to your genetically modified tomato with a delayed ripening trait about which you initiated consultations with the agency in March 1993. The new tomato variety has been modified for delayed ripening by insertion of a fragment of the tomato aminocyclopropane carboxylic acid synthase gene using the Transwitch™ gene suppression technology.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new tomato variety on September 16, 1994. On October 4, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by DNA Plant Technology (DNAPT) to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded that the new tomato variety is substantially equivalent in composition, safety, or any other relevant parameter to tomato varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0007 and that will be maintained in the Office of Premarket Approval.

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Based on the description of the data and information presented during the consultations, the new tomato variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is DNAPT's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc: HFS-200 HFS-205 HFS-206 HFS-226 HFS-246 HFS-247
HFS-013 HFV-221 BNF 0007